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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,150	11/19/2001	Dario Cremaschi	216261US0CONT	8275

22850 7590 04/09/2004

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/988,150

Applicant(s)

CREMASCHI ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13, 15-22 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-22 and 24-28 is/are allowed.
- 6) ☒ Claim(s) 11-13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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Re: Cremaschi *et al.*

Date of priority: 04/14/1997

Response to Amendment

The Amendment filed 01/30/2004 in response to the Office Action of November 7, 2003 is acknowledged and has been entered.

Claims 11-13, 15-22, and 24-28 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejection Maintained:

Claims 11-13, 15-19 remain rejected under 35 USC 103(a) as being unpatentable over Smith *et al.* (WO94/28879, IDS) in view of Almeida *et al.* ("Nasal Delivery of Vaccines", Jnl. of Drug Targeting, 1996, Vol. 3, pages 455-467) for the reasons of record in the Action mailed November 7, 2003.

Applicants argue (Response filed 01/30/04, pages 2-3) that the alleged support for intranasal administration in Almeida does not suggest that nasal administration is *better* than oral administration. This argument has been considered but is not found persuasive. First, the passage that applicants rely on (page 461, 2nd column) does not appear to support this argument

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because it is not clear how similar mechanisms of solid particle uptake by the nasal mucosa compared to uptake found in the gut is disadvantageous. Secondly, Almeida *et al.* does indeed suggest that nasal administration is better than oral administration by summarizing the known advantages of administering through this route as set forth in the previous Action mailed November 7, 2003, page 6. Moreover, Almeida *et al.* teach, “ The nasal administration of drugs exploits (emphasis added) the higher permeability of the nasal mucosa when compared to other mucosal surfaces” (page 457, 1st column). The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some *advantage* or expected beneficial result would have been produced by their combination. MPEP 2144.

Applicants further argue that greater than expected results are evidence of nonobviousness wherein applicants submit that nothing in the combined teachings of the cited references suggest nor predict the 400,000 times greater absorption of the microparticle composition in the nasal mucosa compared to the intestine. Applicants further reiterate previous rebuttals by the Office in the comparison of in-vitro data versus *in vivo* data. Applicants submit that experiments preformed *in vitro* (nasal tissue) at lower than physiological temperatures gave greater than expected results compared to *in vivo* (intestinal mucosa) experiments at physiological temperatures of 37⁰C. Since lower incubation temperatures (i.e. 27⁰C) lowers metabolism and transport twice as much, Applicants argue that it would be expected that if the experiments in the nasal mucosa were performed at 37⁰C the resulting increase through the nasal mucosa would have been approximately 800,000 times greater than the intestine. This argument has been considered but is only found persuasive to the extent that the greater than expected rate

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of transepithelial transport is recited in the claims. While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See *Ex parte Oetiker*, 23 USPQ2d 1641 (BPAI, 1992). Applicant is reminded that the claims define the subject matter of his invention and that the specification cannot be relied upon to read limitations into the claims.

Claims 20-22, and 24-28 appear to be allowable.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

April 8, 2004


GARY NICKOL
PRIMARY EXAMINER